REMARKS

Claims 1, 3-8, 10-17 and 19-26 are pending in the application. Claims 1, 7 and 16 have been amended. Claims 25 and 26 are new. Claims 3-6 are allowed. No new matter has been added.

Claims 1, 7 and16 have been rejected under 35 USC 112, first paragraph.

The claims have been amended to address this rejection. Support for the amendments to claims 1, 7 and 16 and new claims 25 and 26 is found in the specification at page 13, first paragraph. Further, please see page 13, second paragraph (lines 17-19) of the specification for a description of "immune system potentiating amounts of thymosin." This portion of the description also provides support for thymosin-α and fragments thereof as found in amendments to claims 1 and 7. This rejection is now believed overcome.

Claims 7, 8, 10-17, 19-24 have been rejected under 35 USC 103(a) as allegedly unpatentable over Huang, et al. in view of Hoofnagle et al. and further in view of Horecker. Applicant traverses this rejection.

The present invention is directed to a method of treating a mammal infected with Hepatitis C virus with a combination therapy of α-interferon and thymosin α (claim 1). The present invention is also directed to a composition comprising a pharmaceutical dosage unit of a pharmaceutically acceptable carrier containing an immune system potentiating amount of at least one thymosin in combination with an anti-hepatitis C viral effective amount of at least one α-interferon (claim 7). The Applicant has found that improved results are achieved with a combination therapy over using either α-interferon alone or Thymosin α alone. No one in the literature or otherwise has ever suggested using thymosin for the treatment of Hepatitis C. Also, no one in the literature or otherwise used or suggested the use of the two ingredients together at the time of the invention.

None of the cited references, whether taken alone or in combination suggest the combination of these two ingredients as a suitable and effective means for treating Hepatitis C.

Before the references are discussed, it is important understand that that the subject of this invention, Hepatitis C, is caused by an RNA virus. On the other hand, Hepatitis B is caused by a DNA virus. These two types of viruses operate differently in a host. For Hepatitis C, the injury is mostly caused by the virus itself. For Hepatitis B, the injury is caused by the immunologic response to the virus. Therefore, no generalized assumption would have been made by one of ordinary skill in the art that a therapy that works for Hepatitis B would work for Hepatitis C.

Huang et al. is directed to a composition for treating Hepatitis B rather than Hepatitis C. Huang et al. combines interferon and thymosin to treat Hepatitis B. Huang, et al. is silent about Hepatitis C. Huang et al. also does not disclose what type of interferon is used. Specifically, Huang et al. does not disclose the use of α-interferon. The present composition claims require "an anti-Hepatitis C viral effective amount of at least one α-interferon, said pharmaceutical dosage unit being capable of promoting *in vivo* inactivation of hepatitis C virus." The present method claims call for treating Hepatitis C by administering to a mammal an anti-hepatitis C viral effective amount of at least one α-interferon, concurrently or sequentially with administering a thymosin or thymosin fragment. Huang et al. does not indicate that thymosin is useful for treating Hepatatic C and, therefore, does not lead the artisan to the claims of the invention.

Further, it cannot be said that Huang, et al. anticipates the present claims as suggested by the Examiner. Huang, et al. does not disclose the type of interferon or the type of thymosin. Therefore, the composition of Huang, et al. cannot be expected to be present in the claims, especially when there is no motivation to use the claimed ingredients together to treat Hepatitis C.

Hoofnagle, et al. does not make up for the deficiencies of Huang, et al. Hoofnagle et al. discloses a composition containing α-interferon for treating Hepatitis C. There is no mention of the use of thymosin for treating Hepatitis C or the combination of α-interferon with thymosin for treating Hepatitis C. There is also no suggestion of what the proper dosage unit of thymosin would be or what parameters would be useful to achieve the proper dosage unit of thymosin for the combination therapy of the claims. Although, Hoofnagle, et al. briefly discusses using *other antiviral agents or corticosteroids* in treating Hepatitis C in patients with suspected Hepatitis C who have

not responded to alpha interferon, Hoofnagle, et al. does not suggest using immune system potentiating agents for treating Hepatitis C (page 261, col 2, last paragraph). Without any motivation present in, Hoofnagle et al. to use an immune system potentiating agent such as thymosin, Hoofnagle, et al. would not have lead the skilled artisan to the present invention.

Horecker (US Patent No. 4,614,731) is directed to a peptide having immunopotentiating activity similar to thymosin alpha. It states that a new biologically active polypeptide hormone, thymosin alpha 11, has been isolated from calf thymosin fraction 5. Thymosin alpha 11 contains seven additional amino acid residues at the carboxy terminus when compared to thymosin alpha 1. Although it further states that thymosin is "effective in increasing T cell numbers and normalizing immune function in children with *thymic dependent primary immunodeficiency disease* and can increase T cell numbers in *immunodepressed cancer patients*," it is silent to the treatment of Hepatitis C (col. 1, lines 15-22). It must be pointed out again that Hepatitis C is caused by an RNA virus and the injury is caused by the virus itself. The studied treatment described in Horecker is not for the Hepatitis C virus or like disease, it is for immunodeficiency diseases, immunodepressed cancer patients and for the prevention of opportunistic infections in immunosuppressed patients (col. 1, lines 30-39).

There must be some motivation for (1) the use of thymosin with interferon and (2) this combination of thymosin with interferon for the treatment of Hepatitis C for Horecker to be successfully combined with the other references. In this case, there is not. Not only is there no combined therapy in Horecker, there is no use of thymosin for the treatment of Hepatitis C or any other viral entity.

Therefore, Horecker does not add to the disclosures of the above two references in such a way that would have motivated one of ordinary skill in the art to try thymosin with α-interferon to treat an RNA virus like Hepatitis C.

Applicant states that a doctor of ordinary skill in the art would not have automatically combined therapies of antiviral agents and immune potentiating agents for a particular disease without a great deal of experimentation because of the fear of side effects or the canceling of effectiveness or otherwise. It is respectfully submitted that the combination of Huang, et al., Hoofnagle, et al. and Horecker would not have motivated

one of ordinary skill in the art at the time of the invention to arrive at the present claims under 35 USC §103(a).

Reconsideration and allowance are respectfully requested.

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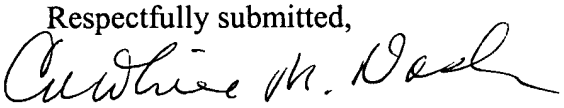
Respectfully submitted,



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